

REMARKS

Favorable consideration and allowance are respectfully requested for claims 1-4 in view of the following remarks

A "CROSS-REFERENCE TO RELATED APPLICATIONS" paragraph is added as requested by the Examiner on page 2 of the recent Office Action.

The title of the invention is amended to read "Method of Preparing Pharmaceutical Compositions."

An Application Data Sheet is submitted herewith providing the city and foreign country of residence of each inventor. Therefore, a new oath or declaration is not required.

The rejection of claims 1 – 4 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement is respectfully traversed.

The present application claims a method of preparing a pharmaceutical composition for treating or inhibiting obesity. The method comprises the steps of identifying compounds which inhibit *de novo* lipogenesis activity in mammals, especially man; and incorporating selected compounds which are capable of inhibiting *de novo* lipogenesis activity in mammals, especially man, into a pharmaceutically administrable dosage form. The first method step is exemplified on page 7, first paragraph of the specification where a test protocol for the identification process is described. The protocol involves: measuring the inhibition of the activity of at least one carboanhydrase by, e.g., bringing a test compound into contact with a carboanhydrase and identifying or selecting those compounds which inhibit the activity of that carboanhydrase. Preferred embodiments are further disclosed in the second part of that paragraph where carboanhydrases which occur in mammals such as man or rats, for example rats, mice or guinea-pigs, especially carboanhydrases of subtypes II and/or V are specified. Particularly preferred *in vitro* test methods of determining the inhibition of the carboanhydrase activity are further defined in the paragraph

bridging pages 7 and 8, including several methods for carrying out these tests (for instance on pages 7 to 10 of the specification as originally filed).

Topiramate was provided as an example of a compound which might be identified as a carbonic anhydrase inhibitor using the inventive screening method as described beginning on page 9, second paragraph. Topiramate was selected because the treatment of obesity with topiramate is known (please see WO 98/00130 [Shank]). The use of topiramate as test compound demonstrates the suitability and the effectiveness of the presently claimed method. Because topiramate is provided only as an example to demonstrate the practicability of a particular embodiment of the claimed method, whether topiramate could be used with each step provided in each of the claims is irrelevant to the patentability of the claims as a whole. The claims are allowable regardless of whether topiramate might fit within the limitations of each of these claims.

The realization of the underlying operative mechanism for weight-lowering effects provides the characteristic to be screened for in identifying suitable compounds. Because the claims recite this operative mechanism, the method serves to justify the claims over their full breadth.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail so that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The parent application, with substantially the same specification and with claims directed to, *inter alia*, methods of identifying compounds for inhibiting obesity, has issued as U.S. Patent No. 6,946,243. Accordingly, the PTO has determined the screening method is adequately described. The present claims

add the step of incorporating a compound identified through the screening into a pharmaceutical form. Methods of incorporating such compounds into pharmaceutical formulations are provided at least on pages 13 and 15 of the specification.

Accordingly, a person of skill in the art would reasonably conclude that the applicants had possession of the invention as claimed, and reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 1 - 3 under 35 U.S.C. §103(a) over Applicants' alleged admissions in the specification and Shank (WO 98/00130) is respectfully traversed.

The present claims are directed to a method of preparing a pharmaceutical composition for treating or inhibiting obesity. This method involves identifying compounds which inhibit *de novo* lipogenesis activity in mammals, especially man; and incorporating selected compounds which are capable of inhibiting *de novo* lipogenesis activity in mammals, especially man, into a pharmaceutically administrable dosage form.

In contrast to the present invention, Shank (WO 98/00130) discloses topiramate and structurally related compounds, their preparation and use for the treatment of obesity. Shank (WO 98/00130) mentions that topiramate would be suitable for the treatment of obesity by referring to certain studies (page 2, lines 11 to 13 of Shank (WO 98/00130)) without disclosing relevant pharmacological data.

It is respectfully submitted that Shank (WO 98/00130) does not disclose the method of the present invention, i.e., a method of identifying compounds for the treatment and/or prophylaxis of obesity, whereby *de novo* lipogenesis inhibition activity in mammals, is tested and used as a selection criteria for screening compounds for selection.

Further, Shank (WO 98/00130) provides a person of skill in the art of pharmacological test methods with no incentive to even try to develop the selection criteria of the presently-claimed method. In this regard, Shank (WO

98/00130) is completely silent as to any *de novo* lipogenesis inhibiting activity of topiramate and its structurally related compounds.

The effectiveness and suitability of the presently-claimed invention were evaluated using topiramate as a candidate compound. The methods showed that topiramate indeed inhibits *de novo* lipogenesis activity. This explains the reasoning behind the usage of topiramate for the treatment and/or prophylaxis of obesity.

The claims do not cover novel compounds for treating obesity, rather, the claimed invention relates to a method involving screening to identify suitable compounds for treating or inhibiting obesity and then incorporating selected compounds into pharmaceutical dosage forms. Shank (WO 98/00130) fails to provide one of skill in the art with any motivation to screen for *de novo* lipogenesis inhibition. The present specification does not indicate that it was known to try to screen for *de novo* lipogenesis inhibition. Knowledge that topiramate is suitable for treating obesity does not obviate the present claims as this knowledge provides one of skill in the art with little to no information as to what biological activity might indicate suitability of a test compound for therapeutic use in treating or inhibiting obesity.

Even the recent Office Action indicates that the claims differ from the references in that the claims include steps to identify the compound for treating. Indeed, claims directed to the screening method were already allowed as U.S. Patent No. 6,946,243. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 1 – 4 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is respectfully traversed.

Claim 1 recites “incorporating said compound which inhibits *de novo* lipogenesis into a pharmaceutically administrable dosage form.” By incorporating a compound into a pharmaceutically administrable dosage form, a person practicing the claimed method would necessarily arrive at a

pharmaceutical composition. Claim 2-4 depend from claim 1 and include all of the limitations thereof.

For purposes of definiteness, the relevant question is whether one of skill in the art could understand the scope of the claim. The MPEP states that:

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000).

In the present case, that test is met because one of skill in the art would readily understand that the claims require incorporating a compound into a pharmaceutically administrable dosage form and that by doing so, the person practicing the claimed method arrives at a pharmaceutical composition.

Accordingly, the claims are definite and reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket No. 029300.49991D1).

Respectfully submitted,

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